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10/627,886

07/24/2003

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EXAMINER

KUBELIK, ANNE R

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

06/26/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/627,886 | Applicant(s) SCHMIDT ET AL. | |
| | Examiner Anne R. Kubelik | Art Unit 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 29 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-10 and 12-26 is/are rejected.
- 7) ☒ Claim(s) 6, 7, 11, 27 and 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-28 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The rejection of claims 1, 3-5, 8, 10, 21 and 25 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gupta et al (1982, Mol. Gen. Genet. 188:378-383) taken with the evidence of the instant specification is withdrawn in light of Applicant's amendment to the claims.

Claim Rejections - 35 USC § 102

4. Claims 1-5 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Long et al (1994, Plant Physiol. 105:115). The rejection is repeated for the reasons of record as set forth in the Office action mailed 29 October 2007. Applicant's arguments filed 29 April 2008 have been fully considered but they are not persuasive.

Long et al teach a method of increasing nitrogen metabolism in plant cells by transformation with a construct encoding a bacterial glutamate dehydrogenase, which would inherently increase the assimilation of inorganic nitrogen (in the form of ammonium) into organic nitrogen. The GDH is operably linked to a chloroplast transit peptide and the construct comprises a polyadenylation sequence. The coding sequence has been altered to use plant-favored codons. The transformed cells would inherently have increased biomass or carbon/nitrogen levels.

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Applicant urges that the reference is not enabling because it provides no expectation of success and no details are provided - no DNA sequence information, no source plasmid, no restriction enzyme cleavage, no transformation methods (response pg 6).

This is not found persuasive. The reference provides every expectation of success. In the communication filed 19 December 2001 in the of the instant parent application 09.070,844, Applicant asserted that bacterial GDH sequences were known as early as 1983 and submitted an extensive list of known sequences in GENBANK. Basic cloning techniques, transformation methods, polyadenylation sites, transit peptides, etc were well-known in the art - see, for example, all the references dating from the 1980's cited in the instant specification, in the paragraph spanning pg 14-15. What is well-known in the art need not be taught. It is noted, however, that Applicant claims a plant transformed with a nucleic acid encoding a bacterial GDH, but the specification does not teach the sequence of a bacterial enzyme - is Applicant also arguing that their invention is not enabled? Plant targeting sequences are well-known, as is plant codon optimization.

Applicant urges that there is no proof that any transgenic plant or plant cell was obtained (response pg 6).

This is not found persuasive because Long teaches the claimed method, thus, a transgenic plant cell was obtained.

Applicant urges that Long et al does tell the outcome (response pg 6).

This is not found persuasive because nitrogen metabolism would be inherently altered by the method. The claims are drawn to either increasing or decreasing nitrogen metabolism.

Long's process would inherently modify nitrogen metabolism. The instant specification shows that observable effects would be obtained.

Applicant urges that no guidance is provided as to what alterations were made (response pg 6).

This is not found persuasive because the 3' non-coding region has been altered to ensure appropriate polyadenylation, and codons have been altered to those known in the art to not inhibit expression in plants.

Applicant urges that to be anticipatory, a reference must be enabling; no starting materials are disclosed here (response pg 7).

This is not found persuasive because the starting materials and method steps were well-known in the art.

Claim Rejections - 35 USC § 103

5. Claims 1-5, 8-10 and 12-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Long et al (1994, Plant Physiol. 105:115). The rejection is repeated for the reasons of record as set forth in the Office action mailed 29 October 2007. Applicant's arguments filed 29 April 2008 have been fully considered but they are not persuasive.

The claims are drawn to a method of increasing or decreasing nitrogen metabolism in a plant by transformation of a gene encoding GDH.

Long et al disclose a method of increasing or decreasing nitrogen metabolism in plant cells by transformation of a gene encoding GDH, as discussed above. Long et al do not disclose regeneration of those cells into whole plants.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of increasing or decreasing nitrogen metabolism in plant cells by transformation of a gene encoding GDH as taught by Long et al, to regenerate those cells into plants. One of ordinary skill in the art would have been motivated to do so to evaluate the performance of the plants in the field. One of ordinary skill in the art would also have been motivated to transform the DNA into economically important dicots like tobacco or Brassica and economically important monocots like Zea mays, as altering nitrogen metabolism in a plant would alter the plant's yield. One of ordinary skill would have been motivated to use a constitutive promoter like 35S, as this is the most commonly used promoter in plant transformation.

The arguments made in response to the 102 rejection over Long et al are also made in response to this rejection; these arguments and the answers above are not repeated.

Applicant urges that Long et al only provides a suggestion to experiment, with no specifics to provide the ordinary artisan an expectation of success (response pg 7).

This is not found persuasive because one of ordinary skill in the art would have been able to supply those specifics using routine techniques in the art. Applicant presented no arguments as to why one of ordinary skill in the art could not fill in any blanks in Long's teachings - why couldn't one of ordinary skill in the art use readily available bacterial sequences, determine which restriction enzymes and transformation vectors would be appropriate, and use plant transformation techniques available in the art? Applicant is reminded that the level of skill in the art is very high. Applicant presented no arguments as to why one would not expect success from Long's teachings, and cannot, given the effects Applicant obtained.

Only a reasonable expectation of success is required for determinations of obviousness, as taught in *In re O'Farrell*, 7 USPQ 2d 1673, 1681 (Fed. Cir. 1988).

6. Claims 1-4, 10, 12-13, 16, 18, 21-22 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gupta et al (1982, Mol. Gen. Genet. 188:378-383).

The claims are drawn to a method of increasing or decreasing nitrogen metabolism in a plant by transformation of a gene encoding GDH.

Gupta et al teach transformation of cells from tobacco mutant *cnx-68* with DNA from *Physalis minima* or *Datura innoxia* (pg 379, left column, paragraphs 4-5); the resulting transformants were able to grow on nitrate as the only nitrogen source, thus increasing their assimilation of inorganic nitrogen into organic nitrogen (paragraph spanning ph 379-380). The total nitrogen level was increased in the transformants compared to nontransformants, because they grew. The normal levels of NADP-dependent glutamate dehydrogenase in the transformants, compared to absence of the enzyme in the mutant (pg 381, right column, paragraph 2) indicates that DNA encoding either the alpha or beta subunit of NADP-dependent glutamate dehydrogenase was transformed into the cells.

Gupta et al do not teach transformation of tobacco with recombinant constructs encoding GDH.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the method of increasing nitrogen metabolism in plant cells by transformation with genomic DNA as taught by Gupta et al to transform the cells with recombinant constructs encoding the alpha or beta subunit of GDH using a readily available GDH sequence in the art. One of ordinary skill in the art would have been motivated to do so to

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confirm that GDH is the enzyme responsible for the effect Gupta et al see. One of ordinary skill in the art would have been motivated to regenerate the cells into plants to further evaluate the effect. One of ordinary skill would have been motivated to use a constitutive promoter like 35S, as this is the most commonly used promoter in plant transformation, and one of skill in the art would use a transcription terminator to get effective expression of the gene.

7. Claims 6-7, 11 and 27-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is

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(866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne Kubelik, Ph.D.

June 27, 2008

/Anne R. Kubelik/

Primary Examiner, Art Unit 1638